UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,001	01/21/2005	Walter Gumbrecht	32860-000834/US	1704

30596 7590 05/18/2007
HARNESS, DICKEY & PIERCE, P.L.C.
P.O.BOX 8910
RESTON, VA 20195

EXAMINER	
CROW, ROBERT THOMAS	
ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
05/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,001	GUMBRECHT ET AL.	
	Examiner	Art Unit	
	Robert T. Crow	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *16-27 and 29-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on 8 March 2007 is acknowledged. The traversal is on the ground(s) that the search would not be burdensome. This is not found persuasive because the claims of the instant 371 national stage application were found to lack unity of invention (where unity of invention requires a special technical feature) due to the lack of a special technical feature between the different groups. Thus the burden of the search of these different inventions is moot.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 16-27 and 29-31 are therefore withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8 March 2007.

3. Claims 1-15 and 28 are under prosecution.

Information Disclosure Statement

4. The Information Disclosure Statement filed 21 January 2005 is acknowledged. However, only the Abstracts of documents DE 39 08 123 A1, WO 02/073153 A2, DE 199 52 723 A1, and DE 100 36 175 A1 are being considered because English language translations of the remainder of the documents have not been provided.

Specification

5. The Substitute Specification filed 21 January 2005 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-15 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-15 and 28 are indefinite in claim 1, which recites the limitation "the sample of measurement liquid" in line 5 of claim 1. The recitation "the samples of measurement liquid" lacks antecedent basis in the "a measurement liquid" in line 4 of claim 1. It is suggested that the claim be amended to reflect proper antecedent basis, and that the amendment be applied to the recitation of "the measurement liquid samples" as recited in line 2 of claim 2.

Claim 3 is indefinite in the recitation "the measurement sample" in line 2 of the claim because "the measurement sample" lacks antecedent basis in either "a measurement liquid" of claim 1 or "the measurement liquid samples" of claim 2. It is suggested that the claim be amended to reflect proper antecedent basis.

Claim 4 is indefinite in the recitation "the sample application" at the end of the claim because "the sample application" lacks antecedent basis in the "applying a measurement liquid" claim 1. It is suggested that the claim be amended to reflect proper antecedent basis.

Claims 5-11 and 14-15 are indefinite in claims 5-7 and 14, each of which recites "spot array(s)" in lines 1 and 2 of claim 5 and in line 2 of each of claims 6-7 and 14. It is unclear if a "spot array" is the biochip of claim 1.

Claims 7 and 28 are each indefinite in the recitation "serves for air conditioning of the gas phase present above a spot array" at the end of each of claims 7 and 28. The recitation is indefinite because no

active method step is recited that results in the air conditioning of the gas phase. It is suggested the claim be amended to include an active method step that results in air conditioning.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5, 7, 9-11, and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Chateau (U.S. Patent No. 4,071,315, issued 31 January 1978).

Regarding claim 1, Chateau teaches a method for performing a high throughput analysis. In a single exemplary embodiment, Chateau teaches a method comprising a biochip with a multiplicity of successive areas 13 (column 5, lines 10-30). Chateau also teaches the tape has spots on the biochip in the form of antibodies pre-attached to the tape (column 3, lines 50-57) having several antigen specimens (Abstract) are placed side by side along the tape (column 2, lines 57-66) in each area. Thus, a side by side placement of several antigens along the antibody tape is a biochip, which has a multiplicity of spots in the form of the two side by side deposits of antigens.

Chateau further teaches the biochips are situated in a carrier in the form of a longitudinal tape that allows continuous analysis of the plurality of samples (Abstract). A measurement liquid, in the form of an enzymatic compound for amplifying the reaction result, is then deposited simultaneously to the spots of the biochips (i.e., areas 13) by needle 28 (column 6, lines 10-33). Chateau also teaches analyzing the samples of measurement liquid, wherein applying and analyzing are effected simultaneously at different spots; namely, depositing and processing (i.e., analyzing) of several side by side specimens (i.e., spots) occurs simultaneously with the recording (i.e., measuring) of information regarding each specimen

and the treatment that is given to each specimen (column 2, lines 57-67). The carrier is moved to permit a continuous measurement at a speed determined by a movement cycle of the carrier; namely, depositing stations are multiplied so that multiple simultaneous analyses are carried out by the machine, wherein the tape is progressed by a number of areas as part of the depositing and analysis (column 5, lines 10-30). The progression of the tape is a movement cycle.

Regarding claims 2 and 4, Chateau teaches the method of claims 1, wherein temperature regulation and air conditioning is interposed between the applying and analyzing; namely, the tape proceeds through incubation enclosure 31 after depositing the measurement liquid by needle 28 but before the tape reaches result reading station 36 (Figure 2). The incubation enclosure 31 is identical to incubation enclosure 20, which controls temperature and humidity (column 5, lines 59-60 and claim 4); thus, temperature and air conditioning are interposed on the sample.

Regarding claim 3, Chateau teaches the method of claim 2, wherein air condition serves as residence time of the measurement sample on the biochip; namely, the air conditioning in incubation enclosure 31 controls the humidity of the deposited sample (column 4, lines 59-60 and claim 4) for a specific period of time (column 8, lines 15-20).

Regarding claim 5, Chateau teaches the method of claim 1, wherein at least one spot array is enclosed by a hollow body in order to create a spatial separation from other spot arrays; namely, the carrier tape is run through enclosure 31 (Figure 2). Because at least one area 13 is held in the enclosure (column 5, lines 59-60 and claim 4), at least one spot array is held therein and is spatially separated from other spot arrays.

Regarding claim 7, Chateau teaches the method of claim 5, wherein the hollow body serves for air conditioning of the gas phase present above a spot array; namely, the spot arrays are the biochips, which are contained in enclosure 31, which is a hollow body. Because hollow body enclosure 31 controls the temperature and humidity of the deposited sample (column 4, lines 59-60 and claim 4), the gas phase (i.e., the air) above the spot array is air conditioned.

Regarding claim 9, Chateau teaches the method of claim 5, wherein the carrier is made of a flat material; namely, a flat tape (Figures 1 and 2 and column 4, lines 28-39).

Regarding claim 10, Chateau teaches the method of claim 9, wherein the a biochip arrangement with a tape-type carrier made of flexible material is used (Figures 1 and 2 and column 4, lines 28-39).

Regarding claim 11, Chateau teaches the method of claim 11, wherein the tape type carrier is unwound from the roll in cartridge 2 (Figure 2 and column 4, lines 45-55) and transported through reading station 36, which is an analysis unit (Figure 2 and column 7, lines 33-50).

Regarding claim 13, Chateau teaches the method of claim 1, wherein the carrier has analysis specific data present; namely, the each spot on the carrier has data relating the specimen and specimen treatment, which is analysis specific data, recorded along the side of the tape next to each spot (column 2, lines 57-66).

Regarding claim 14, Chateau teaches the method of claim 1, wherein heat is supplied or dissipated from the rear side region of the carrier opposite to the array; namely, the tape is heated in enclosure 31 (column 4, lines 59-60 and claim 4). Because the entire enclosure 31 is heated, at least some heat is supplied or dissipated from the rear side region of the tape.

Regarding claim 15, Chateau teaches the method of claim 14, wherein a rear side region is brought into areal contact with a coolable or heatable body; namely, the tape is heated in enclosure 31 (column 4, lines 59-60 and claim 4). Because the entire enclosure 31 is heated, the air gasses within the enclosure contact the rear of the carrier. The air gasses within the enclosure are a gaseous body that is coolable or heatable.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 5-6, 8, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chateau (U.S. Patent No. 4,071,315, issued 31 January 1978) in view of Chetverin et al (U.S. Patent No. 6,103,463, issued 15 August 2000).

It is noted that while claim 5 has been broadly rejected under 35 USC 102(b) as described above on pages 4-5, the claim is also obvious as interpreted by the more narrow interpretation outlined below.

Regarding claim 5, Chateau teaches the method of claim 1 for performing a high throughput analysis. In a single exemplary embodiment, Chateau teaches a method comprising a biochip with a multiplicity of successive areas 13 (column 5, lines 10-30). Chateau also teaches the tape has spots on the biochip in the form of antibodies pre-attached to the tape (column 3, lines 50-57) having several antigen specimens (Abstract) are placed side by side along the tape (column 2, lines 57-66) in each area. Thus,

each side by side placement of antigens along the antibody tape is a biochip, which has a multiplicity of spots in the form of the side by side deposits of antigens.

Chateau further teaches the biochips are situated in a carrier in the form of a longitudinal tape that allows continuous analysis of the plurality of samples (Abstract). A measurement liquid, in the form of an enzymatic compound for amplifying the reaction result, is then deposited simultaneously to the spots of the biochips (i.e., areas 13) by needle 28 (column 6, lines 10-33). Chateau also teaches analyzing the samples of measurement liquid, wherein applying and analyzing are effected simultaneously at different spots; namely, depositing and processing (i.e., analyzing) of several side by side specimens (i.e., spots) occurs simultaneously with the recording (i.e., measuring) of information regarding each specimen and the treatment that is given to each specimen (column 2, lines 57-67). The carrier is moved to permit a continuous measurement at a speed determined by a movement cycle of the carrier; namely, depositing stations are multiplied so that multiple simultaneous analyses are carried out by the machine, wherein the tape is progressed by a number of areas as part of the depositing and analysis (column 5, lines 10-30). The progression of the tape is a movement cycle.

Chateau et al does not teach the narrow interpretation of claim 5, wherein the spot arrays (i.e., biochips) are enclosed by hollow bodies, in the form of an array of wells, in order to create a spatial separation from other spot arrays.

However, Chetverin et al teach at least one biochip, which is at least one spot array, wherein the measurement spots are enclosed by hollow bodies in order to create spatial separation; namely, Chetverin et al teach a spot array contained in an array of wells in the form of a sectioned binary array having a lattice applied to the solid support (Figure 3 and column 10, lines 16-67), wherein the array is on a tape as a solid support (column 14, lines 13-24) and is sealed with a cover sheet (column 16, lines 54-56). The array of wells on the tape that surround the spot array along with the cover sheet form the hollow body that encloses the biochip. Chetverin et al further teach the sectioned array of wells has the added

advantage of allowing many different reactions to be performed in each of the wells simultaneously (column 4, lines 10-13).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method comprising spot arrays of Chateau with the spot arrays within the hollow body as taught by Chetverin et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a method having the added advantage of allowing many different reactions to be performed in each of the wells simultaneously as taught by Chetverin et al (column 4, lines 10-13).

Regarding claim 6, the method of claim 5 is discussed above. Chateau does not teach the hollow body surrounds the spot array in a sealing fashion with a peripheral wall.

However, Chetverin et al teach the hollow body, which comprises the lattice array of wells of the sectioned binary array (Figure 3 and column 10, lines 16-67) on a tape (column 14, lines 13-24) and is sealed with a cover sheet (column 16, lines 54-56). The array of wells on the tape that surround the spot array along with the cover sheet form the hollow body that encloses the biochip. that is rinsed by washing at a steadily increasing temperature, which has the added advantage of allowing the removal of non-covalently bound material, thereby allowing the spot arrays to serve as permanent banks of sorted probe molecule spots (column 4, lines 40-45).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method of Chateau with the rinsing step as taught by Chetverin et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a method having the added advantage of allowing the removal of non-covalently bound material, thereby allowing the spot arrays to serve as permanent banks of sorted probe molecule spots as explicitly taught by Chetverin et al (column 4, lines 40-45).

Regarding claim 8, the method of claim 6 is discussed above. While Chateau teaches rinsing of the biochips (Abstract), Chateau does not explicitly teach rinsing through an internal space within a hollow body.

However, Chetverin et al teach the hollow body, which comprises the lattice array of wells of the sectioned binary array (Figure 3 and column 10, lines 16-67) on a tape (column 14, lines 13-24) and sealed with a cover sheet (column 16, lines 54-56). The array of wells on the tape that surround the spot array along with the cover sheet form the hollow body that encloses the biochip. A rinsing liquid is conducted through an internal space within the hollow body; namely, the biochip is rinsed by washing the enclosed well-containing lattice, which has the added advantage of allowing release of weakly bound molecules in the measurement liquids to without cross contamination between the wells, thereby preventing undesirable mixing of the specific samples on specific spots of the array with the other sample/spot mixtures of the array (column 18, lines 41-50).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method of Chateau with the rinsing step as taught by Chetverin et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a method having the added advantage of preventing undesirable mixing of the specific samples on specific spots of the array with the other sample/spot mixtures of the array as explicitly taught by Chetverin et al (column 18, lines 41-50).

Regarding claim 28, the method of claim 6 is discussed above. Cheteverin et al further teach the hollow body serves for air conditioning of the gas phase present above a spot array; namely, the sealing action of the cover sheet and lattice results in air conditioning of the gas phase because the gas phase trapped within the sealed array is protected from outside changes in humidity. Thus, the air of the gas phase within is maintained in the same condition with respect to humidity.

11. Claims 1 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chateau (U.S. Patent No. 4,071,315, issued 31 January 1978) in view of Meyerhoff et al (U.S. Patent No. 5,830,680, issued 3 November 1998).

Regarding claim 12, Chateau teaches the method of claim 1 for performing a high throughput analysis. In a single exemplary embodiment, Chateau teaches a method comprising a biochip with a multiplicity of successive areas 13 (column 5, lines 10-30). Chateau also teaches the tape has spots on the biochip in the form of antibodies pre-attached to the tape (column 3, lines 50-57) having several antigen specimens (Abstract) are placed side by side along the tape (column 2, lines 57-66) in each area. Thus, each side by side placement of antigens along the antibody tape is a biochip, which has a multiplicity of spots in the form of the side by side deposits of antigens.

Chateau further teaches the biochips are situated in a carrier in the form of a longitudinal tape that allows continuous analysis of the plurality of samples (Abstract). A measurement liquid, in the form of an enzymatic compound for amplifying the reaction result, is then deposited simultaneously to the spots of the biochips (i.e., areas 13) by needle 28 (column 6, lines 10-33). Chateau also teaches analyzing the samples of measurement liquid, wherein applying and analyzing are effected simultaneously at different spots; namely, depositing and processing (i.e., analyzing) of several side by side specimens (i.e., spots) occurs simultaneously with the recording (i.e., measuring) of information regarding each specimen and the treatment that is given to each specimen (column 2, lines 57-67). The carrier is moved to permit a continuous measurement at a speed determined by a movement cycle of the carrier; namely, depositing stations are multiplied so that multiple simultaneous analyses are carried out by the machine, wherein the tape is progressed by a number of areas as part of the depositing and analysis (column 5, lines 10-30). The progression of the tape is a movement cycle.

While Chateau teaches immobilization of the spots (i.e., antibodies) to the tape (column 3, lines 50-57), Chateau does not teach electrically readable biochips.

It is noted, however, that the method does not require the electrical reading of the biochips. Rather, the claim merely requires the biochips are capable of being electrically readable; e.g., that the spots are immobilized using an electrically readable material.

Meyerhoff et al teach a method comprising the use of a carrier in the form of a microporous membrane having an array of gold electrodes thereon, wherein each gold electrode has a different antibody immobilized thereon (column 9, lines 49-55). The electrodes are formed by coating the carrier with gold (column 5, lines 25-42); thus, a gold coating on the carrier results in an electrically readable biochip. Meyerhoff et al also teach the gold coating results in electrochemical detection of the test sample, which has the added advantage of sample detection unaffected by sample turbidity or colors, thereby allowing direct analysis of whole blood samples (column 3, lines 1-5) without any prior purification steps.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method comprising immobilized antibodies of a biochip on carrier as taught by Chateau with the gold coating for immobilization of the antibodies as taught by Meyerhoff et al with a reasonable expectation of success. The modification would result in an electrically readable biochip. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a method having a biochip having the added advantage of allowing direct analysis of whole blood samples without any prior purification steps as explicitly taught by Meyerhoff et al (column 3, lines 1-5).

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert T. Crow
Examiner
Art Unit 1634

BJ FORMAN, PH.D.
PRIMARY EXAMINER